K993288

DEC 29 1999

SULZER MEDICA

Sulzer Carbomedics Inc.

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Austin, Texas 78752-1793

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510(k) SUMMARY
SULZER CARBOMEDICS CARDIOFIX™ PERICARDIUM

The Sulzer Carbomedics CardioFix™ Pericardium is prepared from bovine pericardium stabilized using a dye-mediated process referred to as the PhotoFix® process. This photooxidation process creates crosslinks in the bovine tissue. No aldehyde chemistry is used during any phase of manufacturing including the tissue fixation or sterilization processes.

The CardioFix™ Pericardium is sterilized by ethylene oxide and is supplied sterile in a sealed container with 22% buffered ethanol solution. The package is designed to facilitate convenient aseptic transfer of the pericardium into the sterile field. Rinsing of the pericardium before implantation is not required. The CardioFix™ Pericardium is available in the following sizes: 1 cm x 1 cm, 4 cm x 4 cm, 6 cm x 8 cm, 8 cm x 14 cm, 10 cm x 16 cm, and 14 cm x 16 cm.

The CardioFix™ Pericardium is indicated for use in (1) intracardiac repair [ventricular repair using a reinforced patch technique (i.e., minimum of double thickness) and atrial repair], (2) great vessel repair and suture line buttressing using a reinforced patch technique (i.e., minimum of double thickness) for applications exposed to peak systolic pressure, and (3) pericardial closure.

Comprehensive *in vitro* performance testing has been performed for the Sulzer Carbomedics CardioFix™ Pericardium and Bio-Vascular Peri-Guard Pericardium predicate device. *In vitro* performance testing performed for the CardioFix™ Pericardium and predicate device, which included uniaxial tension, suture retention, and suture hole elongation provides evidence that the CardioFix™ Pericardium is substantially equivalent to the predicate devices. In addition, animal testing demonstrates acceptable *in vivo* performance for the CardioFix™ Pericardium.

Sulzer Carbomedics considers the CardioFix™ Pericardium to be substantially equivalent to the currently marketed predicate devices.

Common name of the Device:	Cardiovascular Patch
Trade Name or Proprietary Name:	Sulzer Carbomedics CardioFix™ Pericardium
Submitter and Contact Person:	Edward E. Newton Regulatory Affairs Manager 1300 E. Anderson Lane, Austin, TX 78752 Phone: (512) 435-3407 Fax: (512) 435-3350
Submission Submitted on:	September 30, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 1999

Mr. Edward E. Newton
Regulatory Affairs Manager
Sulzer Carbomedics, Inc.
1300 East Anderson Lane
Austin, Texas 78752-1793

Re: K993288
Trade Name: Sulzer Carbomedics CardioFix™ Pericardium
Regulatory Class: II
Product Code: DXZ
Dated: September 30, 1999
Received: October 1, 1999

Dear Mr. Newton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

We note that you have provided an article hypothesizing that aldehyde fixation is a potential precursor for calcification. You also included results of rat subcutaneous implantation tests assessing calcification potential. The results suggest that calcification development is delayed in the CardioFix™ compared to the control device. Since the rat model has not been validated to correlate with the human response regarding calcification, your promotional materials must not imply, even by juxtapositioning of verbiage, that the results of the rat studies are predictive of the human response. Any reference to the rat study must include a caveat that long-term human data are not available, and may not correlate with the results of the rat study.

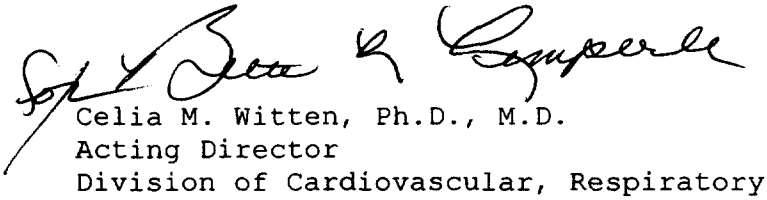
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance

with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): Unknown

Device Name: Sulzer Carbomedics CardioFix™ Pericardium

Indications for Use: Sulzer Carbomedics CardioFix™ Pericardium is indicated for the following uses:

- Intracardiac Repair
  - Ventricular repair using a reinforced patch technique (i.e., minimum of double thickness).
  - Atrial Repair.
- Great vessel repair and suture line buttressing using a reinforced patch technique (i.e., minimum of double thickness) for applications exposed to peak systolic pressure.
- Pericardial Closure.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K 993288

Prescription Use X OR Over-the-Counter Use ____

(Optional Format 1-2-96)